Paper No. 37

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte BEATE GUTTERER

Appeal No. 2003-0855 Application No. 09/147,675

HEARD: June 24, 2003

Before WINTERS, WILLIAM F. SMITH, and SCHEINER, <u>Administrative Patent Judges</u>. WINTERS, Administrative Patent Judge.

DECISION ON APPEAL

This appeal was taken from the examiner's decision rejecting claims 3 through 19, which are all of the claims remaining in the application.

The Invention

The invention relates to a process for increasing the proportion of R-epimer in an R/S-epimer mixture of certain pregna-1,4-diene-3,20-dione 16, 17-acetal 21-esters.

Claim 17, which is illustrative of the subject matter on appeal, reads as follows:

17. A process for increasing the proportion of R-epimer in an R/S-epimer

mixture of compounds of formula I

wherein R1 is 3-8C-cycloalkyl and R2 is 1-7C-alkylcarbonyl or 3-8C-cycloalkylcarbonyl, which comprises subjecting the R/S-epimer mixture of the compounds of formula I to fractional crystallization carried out from a solution of the R/S-epimer mixture of formula I in a mixture of water and a suitable, water-miscible organic solvent (emphasis added).

The Prior Art Reference

In the Examiner's Answer (Paper No. 28), the examiner cites and relies on a single prior art reference:

Jakupovic et al. (Jakupovic) (European Patent Application)

0 262 108 A1

Mar. 30, 1988

The Issue

In the Final Rejection (Paper No. 16), the examiner maintained these rejections: (1) claims 3 through 19 under 35 U.S.C. § 103(a) as unpatentable over the combined

teachings of Uszycka-Horawa,¹ Jakupovic,² and Linus Pauling;³ and (2) claims 3 through 19 under 35 U.S.C. § 103(a) as unpatentable over Jakupovic.² In the

through 19 under 35 U.S.C. § 103(a) as unpatentable over Jakupovic.² In the Examiner's Answer, however, the examiner does not repeat or refer to the former rejection, based on a combination of references; only the latter ground of rejection is maintained (Paper No. 28, § 10). Accordingly, as a matter of standard procedure, the rejection of claims 3 through 19 under 35 U.S.C. § 103(a) as unpatentable over the combined teachings of Uszycka-Horawa, Jakupovic, and Linus Pauling, has been dropped. See Paperless Accounting, Inc. v. Bay Area Rapid Transit System, 804 F.2d 659, 663, 231 USPQ 649, 651-52 (Fed. Cir. 1986), cert. denied, 480 U.S. 933 (1987)(as a matter of standard procedure, rejection not "repeated or referred to" in subsequent Office action(s) has been dropped).

The sole issue presented for review is whether the examiner erred in rejecting claims 3 through 19 under 35 U.S.C. § 103(a) as unpatentable over Jakupovic.

Deliberations

Our deliberations in this matter have included evaluation and review of the following materials: (1) the instant specification, including all of the appealed claims; (2) applicant's Appeal Brief (Paper No. 27) and the Reply Brief (Paper No. 29);

¹ Uszycka-Horawa, PCT Application No. WO92/11280, July 9, 1992

² Jakupovic et al. (Jakupovic), European Patent Application No. 0 262 108 A1 (March 30, 1988)

³ Linus Pauling, <u>General Chemistry</u>, Chapter 2, page 14, last paragraph and page 15, lines 1-2 (W.H. Freeman and Company, San Francisco, Calif. 1947)

(3) the Examiner's Answer (Paper No. 28); and (4) the above-cited Jakupovic reference.

On consideration of the record, including the above-listed materials, we <u>reverse</u> the rejection of claims 3 through 19 under 35 U.S.C. § 103(a) as unpatentable over Jakupovic. Additionally, we recommend that the examiner evaluate the patentability of applicant's claims in light of U.S. Patent No. 5,482,934.

The Examiner's Rejection

In the R/S-epimer mixture of compounds of formula I recited in claim 17, variable R¹ is "3-8C-cycloalkyl" attached at position 22 of the fused ring system. Likewise, claim 8 recites a process for preparing an R/S-epimer mixture of a specific compound, and for increasing the proportion of R-epimer in that mixture, where the specific compound has a cyclohexyl group at position 22 of the fused ring system. Having carefully reviewed the Jakupovic reference in its entirety, we agree with applicant that Jakupovic constitutes insufficient evidence to support a conclusion of obviousness of claims which require that "3-8C-cycloalkyl," or cyclohexyl, be attached at position 22 of the fused ring system.

In a nutshell, the examiner has not established that Jakupovic discloses or suggests a process for preparing the same compounds recited in the claims on appeal.

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The examiner has not established that Jakupovic discloses or suggests a process for preparing any compound where "3-8C-cycloalkyl," or cyclohexyl, is attached at position 22 of the fused ring system. Again, we refer to the definition of variable R¹ in claim 17; and, again, we note that claim 8 is restricted to a process for preparing a specific compound having a cyclohexyl group at position 22 of the fused ring system.

Accordingly, the examiner failed to establish a <u>prima facie</u> case of obviousness of claims 3 through 19 based on the disclosure of Jakupovic alone.

In conclusion, we <u>reverse</u> the examiner's rejection of claims 3 through 19 under 35 U.S.C. § 103(a) as unpatentable over Jakupovic. Where, as here, the examiner failed to establish a <u>prima facie</u> case of obviousness, we find it unnecessary to discuss applicant's declaration evidence submitted to rebut any such prima facie case.

Other Issue

One further matter warrants attention. In the instant specification, page 1, applicant refers to Offenlegungsschrift DE 41 29 535 A1 as relevant prior art. Subsequently, in the "Supplement to Information Disclosure Statement" (Paper No. 25), applicant cites U.S. Patent No. 5,482,934 ('934), issued January 9, 1996 to Calatayud et al. The '934 patent is based on Application No. 278,112, filed July 20, 1994, said to be a continuation of Application No. 578,942, filed September 7, 1990, now abandoned. This means to say that U.S. Patent No. 5,482,934 is the "equivalent" of DE 41 29 535

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A1 which, on its face, seeks the benefit of the filing date of U.S. Application No. 578,942, filed September 7, 1990.4

On return of this application to the examining corps, we recommend that the examiner review U.S. Patent No. 5,482,934 in its entirety. Unlike Jakupovic, the '934 patent discloses compounds which fully meet compounds having formula (I) recited in claim 17 on appeal. In particular, we invite attention to column 10, example VII of the '934 patent disclosing preparation of the same R/S-epimer mixture recited in claim 8 on appeal. Further, example VII of U.S. Patent No. 5,482,934 discloses that:

The mixture of epimers is resolved by preparative HPLC [high-pressure liquid chromatography], using a 7 µm Lichrosorb RP-18 column (250x10) mm i.d.) and ethanol/water as the mobile phase, and obtaining the (22R)epimer practically pure and the (22S)- epimer in a purity greater than 99%.

The product containing the (22R,S)- mixture can also be purified without having to use column chromatography by a method which is described in the following example. [See the '934 patent, column 10, lines 37-44 (emphasis added).1

We recommend that the examiner evaluate the patentability of applicant's process claims in light of U.S. Patent No. 5,482,934, particularly examples VII and VIII.⁵

Conclusion

⁴ Copies of Offenlegungsschrift DE 41 29 535 A1 and U.S. Patent No. 5,482,934 are enclosed with this opinion.

⁵ The record reflects that the examiner previously entered a rejection under 35 U.S.C. § 103(a) based on a combination of references, including DE 41 29 535 A1. See Paper No. 8, page 8; and Paper No. 12, page 7. That rejection has now been withdrawn (Paper No. 16, page 3). But the record does not reflect that the examiner considered an English translation of DE 41 29 535 A1 or that the examiner evaluated the patentability of applicant's process claims in light of U.S. Patent No. 5,482,934.

In conclusion, we <u>reverse</u> the rejection of claims 3 through 19 under 35 U.S.C. § 103(a) as unpatentable over Jakupovic. Additionally, we recommend that the examiner evaluate the patentability of applicant's claims in light of U.S. Patent No. 5,482,934.

The examiner's decision is reversed.

<u>REVERSED</u>

Sherman D. Winters Administrative Patent Judge)))
William F. Smith Administrative Patent Judge)) BOARD OF PATENT
)) APPEALS AND
Toni R. Scheiner)) INTERFERENCES)
Administrative Patent Judge)

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